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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,460	12/11/2000	Jerome B. Zeldis	9516-018	5112
20583	7590	04/06/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EVANS, CHARESSE L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,460

Applicant(s)

ZELDIS, JEROME B.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-18,20-31,43 and 44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4,5,7-18,20-31,43 and 44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Action Summary

Acknowledgment is made of the receipt of applicant's Request for Continued Examination, the Rule 131/132 Affidavit, the Request for Extension for Time, Amendments and Remarks, filed November 21, 2003.

Claims 1, 2, 4, 5, 7-18, 20-31, 43 and 44 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 7-18, 20-31, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims and the nature of the invention are drawn to a method of preventing atherosclerosis in a mammal by administering an effective amount of 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline. The working example on pages

26-27 of the specification describes how to make tablets comprising 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline, but there is no data presented for preventing atherosclerosis. An assertion in the claims necessarily requires evidence of support. However, there is a lack of working examples and guidance in the disclosure demonstrating prophylactic efficacy of atherosclerosis with the instant compound, which is specifically required by the claims. There is no indication in the specification that the instant compound has the properties necessary to prevent atherosclerosis disease.

The state of the art does not teach a preventative treatment for atherosclerosis. Worz et al. (Pharmacotherapy. 2003 May; 25(5):625-37) reviews therapies comprising different tablet formulations of various components to lower cholesterol as a treatment for high cholesterol-related diseases. In addition, Keating et al. (Drugs. 2002; 62 (13): 1909-1944) reviews micronised fenofibrate as a treatment of atherosclerosis dyslipidaemia. Therefore, while the state of the art shows available treatments for lowering cholesterol levels and treating atherosclerosis, there is no teaching in the art that would indicate that a preventative formulation is available to prevent atherosclerosis.

Additionally, there is no guidance provided in the disclosure for administering an "effective amount". Although the specification discusses administering 0.1 mg/kg to 100 mg/kg, there is no evidence presented that would suggest that the amount

disclosed would be effective. Although it is within the skill of the artisan to administer a tablet comprising 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline, it is beyond the skill of the artisan to prevent atherosclerosis with the instant formulation.

Therefore, due to the claims requiring that the instant compound prevent atherosclerosis in the method, the lack of working examples demonstrating preventative efficacy with the instant compound, the lack of art teaching that 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline is an effective prophylactic agent for atherosclerosis, and the lack of guidance in the disclosure for administering an effective amount, it is determined that an undue quantity of experimentation would be required of the skilled artisan to use the invention.

Conclusion

No claims are allowed at this time.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 571-272-0593. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charesse L. Evans
Examiner
Art Unit: 1615

April 1, 2004


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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